

Procter & Gamble - I.P. Division

MAR 16 2005

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**FACSIMILE TRANSMITTAL SHEET AND
CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8****TO: Mail Stop Amendment - United States Patent and Trademark Office****Attn: Examiner Shengjun Wang****Fax No. (703) 872-9306****Phone No. (703) 308-4554**

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- 1) Transmittal for Appeal Brief, and one copy for authorization to charge fee to Deposit Account;
- 2) Appeal Brief (11 pages);

Number of Pages Including this Page: 14**Inventor(s): Resch et al.****S.N.: 10/090,517****Filed: 03/04/2002****Conf. No.: 6459****Case: 8866**

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THE UNITED STATES PATENT AND TRADEMARK OFFICE

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CENTRAL FAX CENTER

MAR 16 2005

Application No. : 10/090,517
Applicant(s) : B. S. Resch et al.
Filed : March 4, 2002
Title : Stable Personal Care Compositions Containing a Retinoid
TC/A.U. : 1617
Examiner : Shengjun Wang
Conf. No. : 6459
Docket No. : 8866
Customer No. : 27752

BRIEF ON APPEALS

Mall Stop Appeal Brief – Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:


Enclosed, pursuant to 37 C.F.R. 1.192(a), is Appellant's brief on Appeal for the above application.

The fee for this Brief on Appeal is \$500.00 pursuant to 37 CFR 1.17(c).

The Director is hereby authorized to charge the above fee, or any additional fees that may be required, or credit any overpayment to Deposit Account No. 16-2480 in the name of The Procter & Gamble Company. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

THE PROCTER & GAMBLE COMPANY

By 
Juliet A. Jones
Registration No. 54,202
(513) 626-2127

March 16, 2005

Customer No. 27752

(BriefonAppealTrans.doc)
(Last Revised 10/10/2003)

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APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir,

This Appeal Brief is submitted in support of the Notice of Appeal transmitted to the PTO via facsimile on January 18, 2005, which set a two-month period for response.

REAL PARTY IN INTEREST

The real party in interest is The Procter & Gamble Company of Cincinnati, Ohio.

RELATED APPEALS AND INTERFERENCES

There are no known related appeals, interferences, or judicial proceedings.

STATUS OF CLAIMS

Claims 1-26 are pending in the present application. Claims 13 and 25 have been withdrawn. Claims 1-12, 14-14 and 26 are appealed. A complete copy of the appealed claims is set forth in the Claims Appendix.

STATUS OF AMENDMENTS

No amendment was filed.

SUMMARY OF CLAIMED SUBJECT MATTER

The present invention relates to a topical personal care composition having improved stability of a retinoid, comprising a retinoid; a preservative selected from the

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group consisting of phenols, phenol salts, quaternium ammonium compounds, halogens, halogen salts, alcohols, inorganic salts, zinc pyrithione, emulsifying preservatives, and mixtures thereof; and a dermatologically acceptable carrier. The composition is substantially free of parahydroxybenzoic acid esters. See specification, page 3, lines 21-28.

The present invention further relates to a topical personal care composition having improved stability of a retinoid, comprising a retinoid selected from the group consisting of retinyl esters, retinyl aldehydes, and mixtures thereof; a preservative; and a dermatologically acceptable carrier. The composition is substantially free of parahydroxybenzoic acid esters, and is substantially free of formaldehyde and formaldehyde donating compounds. See specification, page 3, lines 29-32 through page 4, lines 1-6.

The present invention further relates to a topical personal care composition having improved stability of a retinoid, comprising from about 0.0001% to about 2% of a retinoid (specification, page 6, lines 29-31); an anti-oxidant (specification, page 21, lines 1-4); from about 0.1% to about 0.35% of a preservative selected from the group consisting of carboxylic acid, carboxylic acid salts, and mixtures thereof (specification, page 8, line 20, through page 9, line 4); and a dermatologically acceptable carrier (page 12, lines 17-20). The composition is substantially free of parahydroxybenzoic acid esters and is substantially free of formaldehyde and formaldehyde donating compounds (specification, page 11, line 13 through page 12, line 15).

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Rejection under 35 U.S.C. 103(a) over U.S. Patent No. 6,024,941 in view of U.S. Patent No. 5,939,082 in further view of U.S. Patent No. 5,821,237.

ARGUMENTS

The Examiner has failed to establish a prima facie case of obviousness, and rejection under 35 U.S.C. 103(a) is therefore improper.

Claims 1-12, 14-14 and 26 have been rejected under 35 U.S.C. 103(a) over U.S. Patent 6,024,941, issued to Yanagida et al. (hereinafter "Yanagida"), in view of U.S. Patent No. 5,939,082, issued to Oblong et al. (hereinafter "Oblong") in further view of

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U.S. Patent No. 5,821,237 issued to Bissett et al. (hereinafter "Bissett"). The present invention teaches personal care compositions having improved retinoid stability. An important aspect of the present invention is that the compositions are substantially free of parahydroxybenzoic acid esters, formaldehyde and formaldehyde donating compounds, which Applicants have found contribute significantly to the breakdown of retinoids. Parahydroxybenzoic acid esters include, for example, methylparaben, ethylparaben, propylparaben, isopropylparaben and butylparaben.

Yanagida teaches cosmetic compositions comprising vitamin A compounds (retinoids) and stabilizers selected from a number of well-known stabilizers. Oblong teaches the use of vitamin A in cosmetic compositions, and Bissett teaches the use of preservatives used in the instant composition, for example *o*-phenylphenol. The Office Action concludes that it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to make cosmetic compositions containing the vitamin A compound retinyl propionate, without using parahydroxybenzoic acid esters and formaldehyde donating compounds, and which employ *o*-phenylphenol as a preservative.

Applicants appeal this rejection, and respectfully assert that the Examiner has failed to establish any of the criteria required for a *prima facie* case of obviousness. These criteria include a suggestion or motivation to combine the references, a reasonable expectation of success, and a teaching or suggestion of all the claim limitations. *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438.

A. There is no motivation to combine the references, because the cited art fails to suggest the desirability of excluding parahydroxybenzoic acid esters, formaldehyde and formaldehyde donating compounds to improve retinoid stability.

The problem of vitamin A instability has long been recognized. Yanagida states that "it has been difficult to stably formulate vitamin A into an external skin treatment composition." However, nowhere does the cited art recognize specifically that the presence of parahydroxybenzoic acid esters, formaldehyde and formaldehyde donating compounds contributes to retinoid instability. Conversely, there is no suggestion that the exclusion of these compounds can significantly increase the stability of these compounds.

"The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the

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desirability of the modification.” *In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1786 (Fed. Cir. 1992). Yet the Office Action of February 23, 2004, states on page 4, paragraphs 11 and 12:

Yanagida does not teach to expressly exclude parahydroxybenzoic acid ester[s], or formaldehyde and formaldehyde donating compounds, or [to] employ particular vitamin A derivatives ... or [to] employ [a] particular preservative However, as shows in the claims and the examples, Yanagida et al. do not require the present [sic] of parahydroxybenzoic acid ester[s], or formaldehyde, or its donating compounds.

The Office Action acknowledges, therefore, that the cited art is silent on this issue, and thus fails to suggest the desirability of the modification. In fact, Yanagida, Oblong and Bissett all teach away from the present invention, in that all exemplify the use of parahydroxybenzoic acid esters (methyl- and ethylparaben) in compositions containing retinoids.

Bissett describes compositions which are substantially free of formaldehyde or formaldehyde-donating compounds. However, the purpose is unrelated to increasing retinoid stability, and Bissett therefore also fails to recognize the desirability of the modification. In Bissett, the invention was directed toward stabilization of sulfhydryl compounds (i.e. a highly reactive -SH group). See Bissett, Col. 14, line 67 through Col. 15, line 8. Retinoids contain no sulfhydryl groups. The reactive species in retinoids is oxygen-containing, and the issue is prevention of oxidation. Therefore, one would not be motivated by the teachings of Bissett to exclude formaldehyde and formaldehyde donating compounds to increase retinoid stability.

In light of the foregoing, there is no motivation or suggestion to modify Yanagida based on the teachings of Oblong and Bissett. None of the cited art teaches the desirability of the modification, and all teach away from the present invention. Therefore, Applicants must conclude that only with the benefit of hindsight is there a suggestion of the desirability of the modification. This is an impermissible basis for a rejection under 35 U.S.C. 103(a).

B. There is no reasonable expectation of success.

Combining the references would fail to produce compositions that exhibit the retinoid stability of the compositions of the present invention.

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The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art. *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1124, 56 USPQ2d 1456, 1459 (Fed. Cir. 2000).

Applicants have found that parahydroxybenzoic acid esters, formaldehyde and formaldehyde donating compounds contribute significantly to retinoid instability. All references teach the use of these compounds. Bissett and Oblong fail to address the issue of retinoid stability. Yanagida provides no indication that the compositions exhibit stability comparable to those of the present invention. Applicants therefore could have no reasonable expectation of applying any of the references alone or in combination to successfully produce the compositions of the present invention.

C. The cited art fails to teach or suggest all the claim limitations of the present invention.

Applicants describe personal care compositions with improved retinoid stability, comprising a retinoid; a preservative selected, from among others, phenols; and a dermatologically acceptable carrier; and which are essentially free of parahydroxybenzoic acid esters. As stated above, all of the cited references teach compositions containing parahydroxybenzoic acid esters (methyl- and ethylparaben). Therefore, the combination of references fails to teach or suggest all of the claim limitations.

In summary, Applicants point out that in order to establish a *prima facie* case of obviousness, the Office Action must establish all three of the criteria set forth in *In re Vaeck*. Applicants respectfully submit that the Office Action fails to establish *any* of these criteria. Applicants further reiterate the premise stated in *In re Bisley*:

The discovery of a problem calling for an improvement is often a very essential element in an invention correcting such a problem; and though the problem, once realized, may be solved by use of old and known elements, this does not necessarily negative invention. 197 F.2d 355, 94 USPQ 80, 86-87 (C.C.P.A. 1952).

The Office Action asserts that the claimed invention is obvious "not after [the] 'source of the problem is identified' but before Applicants' claimed invention was made." See Office Action of Sept. 3, 2004, paragraph 7. Applicants assert that in light of the cited art and the arguments presented above, this remedy to the long-standing problem of

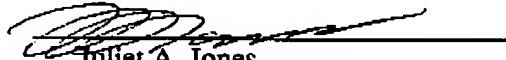
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retinoid instability had not been taught or suggested by the cited art. Only after Applicants accomplished the inventive step of identifying the source of the problem did the remedy become clear. Applicants' invention therefore is non-obvious.

SUMMARY

In light of the arguments set forth above, it is respectfully submitted that the rejection under 35 U.S.C. 103(a) is improper. Applicants respectfully request reversal of the rejection of claims 1-12, 14-14 and 26.

Respectfully submitted,
THE PROCTER & GAMBLE COMPANY


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CLAIMS APPENDIX

1. (Original) A topical personal care composition having improved stability of a retinoid, comprising:
 - a) a retinoid;
 - b) a preservative selected from the group consisting of phenols, phenol salts, quaternium ammonium compounds, halogens, halogen salts, alcohols, inorganic salts, zinc pyrithione, emulsifying preservatives, and mixtures thereof; and
 - c) a dermatologically acceptable carrier;
 - d) wherein the composition is substantially free of parahydroxybenzoic acid esters.
2. (Original) A topical composition according to Claim 1 wherein the composition comprises from about 0.01% to about 0.5%, by weight of the composition, of the retinoid.
3. (Original) A topical composition according to Claim 1 wherein the retinoid is selected from the group consisting of retinol, retinol esters, retinal, retinoic acid, and mixtures thereof.
4. (Original) A topical composition according to Claim 3 wherein the retinoid is selected from the group consisting of retinyl palmitate, retinyl acetate, retinyl propionate, and mixtures thereof.
5. (Original) A topical composition according to Claim 1 wherein the composition comprises from about 0.001 to about 0.25%, by weight of the composition, of the preservative.
6. (Original) A topical composition according to Claim 1 wherein the preservative is selected from the group consisting of quaternium ammonium compounds, phenols, phenol salts, and mixtures thereof.

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7. (Original) A topical composition according to Claim 1 wherein the preservative is selected from the group consisting of pentylene glycol, o-phenylphenol, sodium o-phenylphenol, chlorocresol, salicylic acid, salicylic acid salts, chloroxylenol, thymol, triclosan, cresols, benzalkonium chloride, benzethonium chloride, cetylpyridium chloride, sodium dehydroacetate, chlorhexidine, chlorhexidine salts, chloramine T, triclocarban, iodopropynyl butylcarbanate, chlorobutanol, chlorphenesin, hinokitol, silver chloride, zinc pyrithione, alkyldiaminothylglycine hydrochloride, glycerol caprylate, and mixtures thereof.
8. (Original) A topical composition according to Claim 7 wherein the preservative is selected from the group consisting of pentylene glycol, o-phenylphenol, thymol, benzalkonium chloride, sodium dehydroacetate, chlorhexidine, chlorhexidine gluconate, chloramine T, iodopropynyl butylcarbanate, and mixtures thereof.
9. (Original) A topical composition according to Claim 1 wherein the composition is substantially free of formaldehyde and substantially free of formaldehyde donating materials.
10. (Original) A topical composition according to Claim 1 wherein the composition comprises less than 0.01% of parahydroxybenzoic acid esters.
11. (Original) A topical composition according to Claim 1 wherein the composition further comprises from about 0.01% to about 5% of a preservative enhancer selected from the group consisting of propylene glycol, butylene glycol, EDTA, disodium EDTA, tetrasodium EDTA, and mixtures thereof.
12. (Original) A topical composition according to Claim 1 wherein the composition further comprises a skin care active selected from the group consisting of vitamins, proteins, zeolites, peptides, skin-lightening agents, sunscreen actives, terpene alcohols, desquamation actives, anti-acne actives, anti-wrinkle actives, anti-atrophy actives, anti-

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oxidants, flavanoids, anti-inflammatory agents, anti-cellulite agents, topical anesthetics, tanning actives, skin soothing actives, skin healing actives, conditioning agents, and mixtures thereof

13. (Withdrawn) A method of regulating the condition of skin, said method comprising applying to the skin of a human in need of treatment, a safe and effective amount of a composition according to Claim 1.
14. (Original) A topical personal care composition having improved stability of a retinoid, comprising:
 - a) a retinoid selected from the group consisting of retinyl esters, retinyl aldehydes, and mixtures thereof;
 - b) a preservative; and
 - c) a dermatologically acceptable carrier;
 - d) wherein the composition is substantially free of parahydroxybenzoic acid esters; and
 - e) wherein the composition is substantially free of formaldehyde and formaldehyde donating compounds.
15. (Original) A topical composition according to Claim 14 wherein the composition comprises from about 0.01% to about 0.5%, by weight of the composition, of the retinoid.
16. (Original) A topical composition according to Claim 15 wherein the retinoid is selected from the group consisting of retinyl palmitate, retinyl propionate, retinyl acetate, and mixtures thereof.
17. (Original) A topical composition according to Claim 16 wherein the retinoid is retinyl propionate.

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18. (Original) A topical composition according to Claim 14 wherein the composition comprises from about 0.001 to about 0.25%, by weight of the composition, of the preservative.
19. (Original) A topical composition according to Claim 14 wherein the preservative is selected from the group consisting of phenols, phenol salts, carboxylic acids, carboxylic acid salts, quaternium ammonium compounds, halogens, halogen salts, alcohols, inorganic salts, heterocyclic compounds, emulsifying preservatives, and mixtures thereof.
20. (Original) A topical composition according to Claim 19 wherein the preservative is selected from the group consisting of pentylene glycol, o-phenylphenol, sodium o-phenylphenol, chlorocresol, salicylic acid, sodium salicylate, magnesium salicylate, resorcin, chloroxylonol, thymol, triclosan, cresols, benzalkonium chloride, benzethonium chloride, cetylpyridium chloride, benzoic acid, sodium benzoate, sorbic acid, dehydroacetic acid, sodium dehydroacetate, chlorhexidine, chlorhexidine gluconate, chloramine T, triclocarban, iodopropynyl butylcarbanate, chlorobutanol, chlorphenesin, hinokitol, silver chloride, zinc pyrithione, alkyldiaminothylglycine hydrochloride, glycerol caprylate, and mixtures thereof.
21. (Original) A topical composition according to Claim 20 wherein the preservative is selected from the group consisting of pentylene glycol, o-phenylphenol, thymol, benzalkonium chloride, dehydroacetic acid, sodium dehydroacetate, chlorhexidine, chlorhexidine gluconate, chloramine T, iodopropynyl butylcarbanate, and mixtures thereof.
22. (Original) A topical composition according to Claim 14 wherein the composition comprises less than 0.01% of parahydroxybenzoic acid esters.
23. (Original) A topical composition according to Claim 14 wherein the composition further comprises from about 0.01% to about 5% of a preservative enhancer selected from

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the group consisting of pentylene glycol, butylene glycol, EDTA, disodium EDTA, tetrasodium EDTA, and mixtures thereof.

24. (Original) A topical composition according to Claim 14 wherein the composition further comprises a skin care active selected from the group consisting of vitamins, proteins, zeolites, peptides, skin-lightening agents, sunscreen actives, terpene alcohols, desquamation actives, anti-acne actives, anti-wrinkle actives, anti-atrophy actives, anti-oxidants, flavanoids, anti-inflammatory agents, anti-cellulite agents, topical anesthetics, tanning actives, skin soothing actives, skin healing actives, conditioning agents, and mixtures thereof

25. (Withdrawn) A method of regulating the condition of skin and/or hair, said method comprising applying to the skin and/or hair of a human in need of treatment, a safe and effective amount of a composition according to Claim 14.

26. (Original) A topical personal care composition having improved stability of a retinoid, comprising:

- a) from about 0.0001% to about 2% of a retinoid;
- b) an anti-oxidant;
- c) from about 0.1% to about 0.35% of a preservative selected from the group consisting of carboxylic acid, carboxylic acid salts, and mixtures thereof; and
- d) a dermatologically acceptable carrier;
- e) wherein the composition is substantially free of parahydroxybenzoic acid esters; and
- f) wherein the composition is substantially free of formaldehyde and formaldehyde donating compounds.